

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

Gregory K. Dahlgren,

Case No. 0:10-cv-03827-PAM-JJK

Plaintiff,

v.

**AMENDED ANSWER OF
DEFENDANT DEPUY
ORTHOPAEDICS, INC.**

DePuy Orthopaedics, Inc., and
Saint-Gobain Corporation,

JURY TRIAL DEMANDED

Defendants.

Defendant DePuy Orthopaedics, Inc. (“DePuy”), by and through undersigned counsel, submits the following Amended Answer and Affirmative Defenses to Plaintiff’s Complaint.

DePuy denies each and every allegation, statement, matter and thing contained in Plaintiff’s Complaint except as is hereinafter expressly admitted or alleged.

AS TO PARTIES

1. DePuy is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1 of Plaintiff’s Complaint.

2. DePuy admits it is a corporation organized and existing under the laws of the State of Indiana, with its principal place of business in Warsaw, County of Kosciusko, Indiana, but denies the remaining allegations in paragraph 2 of the Plaintiff’s Complaint.

3. DePuy is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 3 of Plaintiff’s Complaint.

4. DePuy admits that this Court has jurisdiction over this action as alleged in paragraph 4 of Plaintiff's Complaint.

AS TO FACTUAL BACKGROUND

5. DePuy admits the allegations in paragraph 5 of Plaintiff's Complaint, except that it specifically denies that DePuy manufactured the Articul/eze Zirconia Total Hip Ball.

6. DePuy is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 6 of Plaintiff's Complaint which are directed at Saint-Gobain Corporation. Further answering, DePuy admits it sold the Articul/eze Zirconia Total Hip Ball.

7. With respect to the allegations contained in paragraph 7 of Plaintiff's Complaint, DePuy admits that it officially recalled the Articul/eze Zirconia Total Hip Ball, including those bearing catalog number 1365-45-000, on August 13, 2001, in recall number Z-0235-2, and states that its recall notice speaks for itself. DePuy denies that Plaintiff has accurately characterized the reason for the recall or the content of DePuy's recall notice. DePuy denies the remaining allegations in paragraph 7 of Plaintiff's Complaint not expressly admitted.

8. DePuy admits that a recall notice was sent to certain hospitals, which recall notice speaks for itself, and which DePuy admits requested return of certain unimplanted

DePuy Articul/eze Total Hip Balls identified in the notice. DePuy denies the allegations set forth in paragraph 8 of Plaintiff's Complaint.

9. DePuy admits that it marketed the Prodigy Hip System, including the Articul/eze Zirconia Hip Ball and the benefits and risks involved in its use. DePuy denies the remaining allegations in paragraph 9 of Plaintiff's Complaint.

10. DePuy denies that allegations contained in the first sentence in paragraph 10 of Plaintiff's Complaint. Further answering, DePuy states the remaining allegations are incomplete and inaccurate summaries of the scientific articles to which the paragraph refers and that the scientific articles speak for themselves.

11. DePuy is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 11 of Plaintiff's Complaint which are directed at Saint-Gobain Corporation. DePuy specifically denies the allegations contained in the third sentence of paragraph 11 of Plaintiff's Complaint and states that it is without knowledge or information sufficient to form a belief as to the truth of those allegations set forth in the third sentence of paragraph 11 of Plaintiff's Complaint directed at Saint-Gobain Corporation.

12. DePuy is without knowledge of information sufficient to form a belief as to the truth of the allegations set forth in paragraph 12 of Plaintiff's Complaint. DePuy specifically denies the allegations contained in the last sentence of paragraph 12 of Plaintiff's Complaint.

13. DePuy is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 13 of Plaintiff's Complaint.

14. DePuy is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 14 of Plaintiff's Complaint.

15. DePuy is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 15 of Plaintiff's Complaint.

16. DePuy denies the allegations in paragraph 16 of Plaintiff's Complaint.

17. DePuy is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 17 of Plaintiff's Complaint.

18. DePuy is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 18 of Plaintiff's Complaint. DePuy specifically denies the allegations of "early failure" in paragraph 18 of Plaintiff's Complaint.

AS TO THE FIRST CAUSE OF ACTION
(STRICT LIABILITY)

19. DePuy restates, realleges, and incorporates by reference paragraphs 1 through 18 of its amended answer to Plaintiff's Complaint.

20. DePuy denies the allegations set forth in paragraph 20 of Plaintiff's Complaint.

21. DePuy denies the allegations set forth in paragraph 21 of Plaintiff's Complaint.

22. DePuy denies the allegations set forth in paragraph 22 of Plaintiff's Complaint.

23. DePuy denies the allegations set forth in paragraph 23 of Plaintiff's Complaint.

24. DePuy denies the allegations set forth in paragraph 24 of Plaintiff's Complaint.

AS TO THE SECOND CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)

25. DePuy restates, realleges, and incorporates by reference paragraphs 1 through 24 of its amended answer to Plaintiff's Complaint.

26. DePuy denies the allegations set forth in paragraph 26 of Plaintiff's Complaint.

27. DePuy denies the allegations set forth in paragraph 27 of Plaintiff's Complaint.

28. DePuy denies the allegations set forth in paragraph 28 of Plaintiff's Complaint.

AS TO THE THIRD CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY)

29. DePuy restates, realleges, and incorporates by reference paragraphs 1 through 28 of its amended answer to Plaintiff's Complaint.

30. DePuy admits it knew and intended the Articul/eze Zirconia femoral head would be used in hip replacement surgery. DePuy admits only the warranties imposed by law and affirmatively alleges it complied with said duties. DePuy specifically denies the remaining allegations in paragraph 30 of Plaintiff's Complaint.

31. DePuy denies the allegations set forth in paragraph 31 of Plaintiff's Complaint.

32. DePuy denies the allegations set forth in paragraph 32 of Plaintiff's Complaint.

33. DePuy denies the allegations set forth in paragraph 33 of Plaintiff's Complaint.

AS TO THE FOURTH CAUSE OF ACTION
(NEGLIGENCE)

34. DePuy restates, realleges, and incorporates by reference paragraphs 1 through 33 of its amended answer to Plaintiff's Complaint.

35. As to DePuy only, it admits only the duties imposed by law and affirmatively alleges that it complied with said duties. DePuy specifically denies the remaining allegations in paragraph 35 of Plaintiff's Complaint.

36. DePuy denies the allegations set forth in paragraph 36 of Plaintiff's Complaint.

37. DePuy denies the allegations set forth in paragraph 37 of Plaintiff's Complaint.

38. DePuy denies the allegations set forth in paragraph 38 of Plaintiff's Complaint.

AS TO THE FIFTH CAUSE OF ACTION

39. DePuy restates, realleges, and incorporates by reference paragraphs 1 through 38 of its amended answer to Plaintiff's Complaint.

40. DePuy denies the allegations set forth in paragraph 40 of Plaintiff's Complaint.

41. DePuy denies the allegations set forth in paragraph 41 of Plaintiff's Complaint.

42. DePuy denies the allegations set forth in paragraph 42 of Plaintiff's Complaint.

43. DePuy denies the allegations set forth in paragraph 43 of Plaintiff's Complaint.

AS TO DAMAGES

44. DePuy denies the allegations set forth in paragraph 44 of Plaintiff's Complaint.

ADDITIONAL DEFENSES

45. Plaintiff's Complaint fails to state a claim upon which relief may be granted.

46. Plaintiff's claims are barred by the applicable statute of limitations.

47. Plaintiff's claims are barred by the doctrine of laches and/or estoppel.

48. Plaintiff's claims are barred by the doctrines of informed consent, release, and waiver.

49. Plaintiff knowingly, intentionally, and voluntarily assumed any and all risks inherent in the use of the product and/or was contributorily negligent and/or engaged in misuse or abuse of said product, which conduct is a complete bar to Plaintiff's recovery, if any.

50. Plaintiff's claims are barred or reduced by Plaintiff's own comparative and/or contributory fault.

51. Plaintiff's alleged damages or injuries, if any, were caused in whole or in part by Plaintiff's unreasonable, unforeseeable, inappropriate, and/or improper use of the product.

52. Whatever injuries Plaintiff may have sustained were caused in whole or in part by Plaintiff or by someone over whom DePuy had no control.

53. If Plaintiff sustained any of the injuries alleged in the Complaint, which is denied, there was an intervening cause and/or causes leading to said alleged injuries, and

as such any action on the part of DePuy was not the proximate and/or competent producing cause of Plaintiff's alleged injuries.

54. If Plaintiff sustained any of the injuries alleged in the Complaint, which is denied, said injuries were caused in full or in part by the conduct of one or more third persons for whose conduct DePuy is not responsible or with whom DePuy has no legal relationship.

55. Plaintiff's alleged injuries, if any, were caused in whole or in part by pre-existing conditions.

56. Plaintiff has failed to mitigate her damages, if any.

57. Plaintiff has failed to state a claim upon which attorney fees may be awarded.

58. The product identified in Plaintiff's Complaint was approved by the FDA and other government authorities and DePuy acted at all times in compliance with the rules and regulations of the FDA and other governmental authorities.

59. DePuy is entitled to the benefit of all defenses and presumptions which may arise because the design, manufacture, inspection, packaging, issuing of warning and instructions and/or labeling of the product, which is the subject of the Complaint, were in conformity with the generally recognized, reasonably available and reliable state of the art and prevailing standards in the industry at the time the product was manufactured.

60. The product identified in Plaintiff's Complaint was in conformity with the state of the art and/or the state of scientific knowledge at the relevant times involved.

61. At all relevant times, DePuy exercised due care, and its products and its warnings and instructions were governed by and conformed with applicable federal statutes, rules and regulations; therefore, DePuy's product was presumptively not defective and the warnings and instructions relating to its products were presumptively adequate.

62. Plaintiff's claims are barred because the benefits relevant to the product outweighed the risks.

63. Plaintiff's claims are barred by the learned intermediary doctrine.

64. Plaintiff's injuries are the result of a superseding cause.

65. Plaintiff has failed to allege fraud, concealment, or misrepresentation with sufficient particularity.

66. DePuy did not make to Plaintiff, nor did it breach any implied warranties, nor did DePuy breach any warranties created by law. To the extent that Plaintiff relies on any theory of breach of warranty, such claims are barred by applicable law, for lack of reliance, and for lack of privity with DePuy and/or failure of Plaintiff, or Plaintiff's representatives, to give timely notice to DePuy of any alleged breach of warranty. DePuy further specifically pleads as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code existing and which may arise in the future.

67. Affirmatively and alternatively, DePuy pleads the application of the Restatement (Second) of Torts § 402A, cmt. k and Restatement (Third) of Torts: Products Liability §§ 2, 4 and 6 (c) and (d).

68. Plaintiff's claims are preempted, in whole or in part, by federal law under the Supremacy and Due Process Clauses of the United States Constitution.

69. Plaintiff's claims are barred, in whole or in part, because the Food and Drug Administration has exclusive or primary jurisdiction over the matters asserted in Plaintiff's Complaint.

70. Any claims by Plaintiff relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First Amendment rights to petition the government and *Buckman v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001).

71. Plaintiff's claims are barred, in whole or in part, because any alleged representations with respect to the product were not false or misleading and constitute protected speech under the applicable provisions of the United States Constitution, including the First Amendment, and analogous provisions of the Minnesota Constitution.

72. DePuy is entitled to a setoff for all amounts paid, payable by, or available from collateral sources.

73. To the extent not stated above, DePuy raises all affirmative defenses available under the law of the forum in which each respective claim arose.

74. Plaintiff lacks standing because the DePuy did not engage in deceptive conduct with regard to Plaintiff or otherwise.

75. DePuy specifically reserves the right to present other and further defenses after further discovery and investigation herein.

76. Plaintiff's claims may be barred by the provisions of Minn. Stat. § 573.01, *et seq.*

WHEREFORE, this answering DePuy prays that Plaintiff takes nothing by reason of her pretended Complaint and that DePuy have judgment for its costs and disbursements incurred herein.

TRIAL BY JURY IS HEREBY DEMANDED

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, DePuy hereby states its demand for a trial by jury, composed of the maximum number of jurors allowed by law, on all of the issues in this case.

Dated: October 19, 2010

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